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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/535,351 | 04/14/2006 | Samuel R. Denmeade | 50562-P001US | 7060 |
| 61060 | 7590 | 07/07/2010 | EXAMINER | |
| WINSTEAD PC | | | AUDET, MAURY A | |
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| DALLAS, TX 75201 | | | PAPER NUMBER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,351

Applicant(s)

DENMEADE ET AL.

Examiner

MAURY AUDET

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/12/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-53 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-24 and 27-53 is/are rejected.
- 7) ☒ Claim(s) 21-24 and 27-53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment and arguments are acknowledged. The Double Patenting rejection is maintained as the Terminal Disclaimer was disapproved (Applicant mistakenly listed SN 11/725351, **instead of 11/725,135**).

Election/Restrictions

As noted previously, Applicant's election without traverse of Group III, claims 21-53, and the peptide of the invention of SEQ ID NO: 9 (artificial/synthetic peptide sequence of GKAFRR)), in the reply filed on 5/7/09 is acknowledged. Claims 25-26 are withdrawn as not being drawn to the elected invention. As noted in the restriction requirement of 12/8/0, the election of the peptide of SEQ ID NO: 9 was an election of invention (not species) as the compound of the elected Group III. As noted SEQ ID NO: 9 is an independent and distinct invention; a distinct search with no overlapping core with any other peptides (art that would be deemed to read on one would not the other, absent evidence to the contrary which was not filed of record).

Double Patenting-Maintained

The rejection of claims 21-24 and 27-53 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 8, and 17-36 of copending Application No. 11/725,135, is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. The Double Patenting rejection is maintained as the Terminal Disclaimer was disapproved (Applicant mistakenly listed SN 11/725351, **instead of 11/725,135**).

The rejection is repeated below for continuity of record:

Although the conflicting claims are not identical, they are not patentably distinct from each other because presently elected peptide of SEQ ID NO: 9 (artificial/synthetic peptide sequence of GKAFRR) is a species of the genus claims of '135 (see. E.g. claims 17, 1-2, 8, copied below). '135, also titled activation of peptide prodrugs by hK2, is drawn to:

17. A composition comprising a prodrug, the prodrug comprising
a therapeutically active drug; and
a peptide of claim 1,
wherein the peptide is linked to the therapeutically active drug to inhibit the therapeutic activity of the drug, and wherein the therapeutically active drug is cleaved from the peptide upon proteolysis by an enzyme having a proteolytic activity of human kallikrein 2 (hK2).

1. A peptide comprising an amino acid sequence having a cleavage site specific for an enzyme having a proteolytic activity of human kallikrein 2 (hK2), wherein the peptide is 20 or fewer amino acids in length.
2. The peptide of claim 1, wherein the sequence comprises: the amino acids



wherein X_4 is from 0 to 20 amino acids; X_3 is lysine, serine, alanine, histidine or glutamine; X_2 is arginine, phenylalanine, lysine or histidine; and X_1 is arginine, histidine or lysine.

Wherein claim 8 is drawn to a species peptide that may be e.g. GKAFR (5mer core of Applicant's elected 6mer GKAFRR (SEQ ID NO: 9)), which based on the genus claim 2 could add another amino acid and constitute the presently elected peptide. The genus of '135 read in light of its specification, revealing that the presently elected 6mer GKAFRR (SEQ ID NO: 9) is

contemplated therein (specification/sequence listing), it would've thus been obvious for the genus to read on the present species, in this situation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

As noted previously, notwithstanding the Double Patenting rejection above, claims 21-24 and 27-53, as drawn to the elected invention of the peptide of SEQ ID NO: 9 (artificial/synthetic peptide sequence of GKAFRR); was not found to be reasonably taught or suggested by the prior art of record. As noted above, were the claims amended commensurate in scope with the elected invention of the peptide of SEQ ID NO: 9, the claims would likely receive favorable consideration (pending no new art is found on the updated search of the art, to be conducted after response hereto).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 7/2/2010

/Maury Audet/
Primary Examiner, Art Unit 1654